APR 2 5 2003

510(k) Summary

as required by 807.92

K030276

1. Company Identification

Totoku Electric Co., Ltd.
300 Oya, Ueda-shi, Nagano-ken, 386-0192, JAPAN
Tel: 011-81-268-34-5484
Fax: 011-82-268-34-5565

2. Official Correspondent

Mikio Hasegawa (Mr.)
General Manager
Product Development Dept.

3. Date of Submission

Jan. 24, 2003

4. Device Trade Name

Flat Panel Displays, CDL Series

5. Common Name

Monitor, display, workstation, and others

6. Classification

Medical displays are classified as Class I or II per 21 CFR 890.2050

7. Predicate Device

Totoku ME311L 3 Mega Pixel Diagnostic Display, manufactured by Totoku Electric Co., Ltd. (K012099). Comparison of the principle characteristics of the device which is pertinent to clinical performance is shown in Appendix 1.

8. Description of Device

CDL Series Medical Displays are displays for medical use.

9. Intended Use

CDL Series Medical Displays are intended for use in viewing digital medical images.

10. Explanation of CDL Series

CDL Series consists of color LCD displays listed below.

Model No. CDL1811A

Model No. CDL1813A

Comparison of specifications are shown in Appendix 2.

11. Compliance

All CDL Series listed above comply with the following standards.

Medical Safety: UL2601-1, CSA No. 601-1, MDD/CE (EN60601-1, IEC60601-1)

EMC: MDD/CE (EN60601-1-2), IEC60601-1-2, and FCC-B

Appendix 1 Specification Comparison Chart with Predicate Device

Item	ME311L	CDL1811A
510(k) Number	K012099	Not known
Display area	Horizontal:423.9mm, Vertical:318.0mm	Horizontal: 359.0mm, Vertical: 287.2mm
Input signal	GVIF video signal 10214-1210VE (3M:MDR14P)	D-SUB (analog), DVI-D (digital)
Maximum display pixels	Portrait: 1536 dots X 2048 line Landscape: 2048 dots X 1536 line	1280 X 1024 dots
Scanning frequency	Horizontal:93KHz, Vertical:60Hz	Horizontal: 31K - 80KHz, Vertical: 55 - 85Hz
Maximum image clock	65MHz	135MHz
Maxmum brightness	600cd/m2	240cd/m2
Brightness calibration	Software(option) Photosensor(option item)-DTP92(X-Lite)	- -
Serial communication connector	D-sub 9P x 2	15P Mini D-SUB, 24P DVI-D, 4P DC input terminal 9p Mini D-SUB serial (RS232C)
Agency standards	Medical safety:UL2601-1,CSA No.601-1 EN60601-1 MDD/CE:(EN60601-1, EN60601-1-2)	Medical safety: UL2601-1,CSA CSA C22.2No.601.1 (EN60601-1), FCC Class B, DOC-B, BSMI
Dimensions and weight (incl. Tilt and swivel)	Net, 486x480x250mm(W x H x D) (landscape) 11kg 380x533x250mm(W x H x D) (portrait) Packed, 733x642x363mm(W x H x D) 17kg	Net: 432x353x68.6mm(W x H x D) (landscape) 6.9kg Packed: 485x600x280mm(W x H x D) 12kg
Power supply	100-240V AC, 50/60Hz	100-250V AC, 50/60Hz

Appendix 2 **Specification Comparison Chart of the Applied Models**

Item	CDL1811A	CDL1813A
510(k) Number	Not known	Not known
Display area	Horizontal: 359.0mm, Vertical: 287.2mm	Horizontal: 359.0mm, Vertical: 287.2mm
Input signal	D-SUB (analog), DVI-D (digital)	D-SUB (analog), DVI-D (digital)
Maximum display pixels	1280 X 1024 dots	1280 X 1024 dots
Scanning frequency	Horizontal: 31K - 80KHz, Vertical: 55 - 85Hz	Horizontal: 31K - 80KHz, Vertical: 55 - 85Hz
Maximum image clock	135MHz	135MHz
Maxmum brightness	240cd/m2	240cd/m2
Brightness calibration	- -	- -
Serial communication connector	15P Mini D-SUB, 24P DVI-D, 4P DC input terminal 9p Mini D-SUB serial (RS232C)	15P Mini D-SUB, 24P DVI-D, 4P DC input terminal 9p Mini D-SUB serial (RS232C)
Agency standards	Medical safety: UL2601-1,CSA CSA C22.2No.601.1 (EN60601-1), FCC Class B, DOC-B, BSMI	Medical safety: UL2601-1,CSA CSA C22.2No.601.1 (EN60601-1), FCC Class B, DOC-B, BSMI
Dimensions and weight	Net: 432x353x68.6mm(W x H x D) (landscape) 6.9kg Packed: 485x600x280mm(W x H x D) 12kg	Net: 432x353x68.6mm(W x H x D) (landscape) 6.9kg Packed: 485x600x280mm(W x H x D) 12kg
Power supply	100-250V AC, 50/60Hz	100-250V AC, 50/60Hz

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 5 2003

Mr. Mikio Hasegawa
General Manager
Totoku Electric Co., Ltd.
Product Development Dept., MM Company
300 Oya, Ueda-shi
Nagano 286-0192
JAPAN

Re: K030276
Trade/Device Name: Flat Panel Display, CDL Series
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: January 24, 2003
Received: January 27, 2003

Dear Mr. Hasegawa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (If known): Not known K030276

Device Name: Flat Panel Displays, CDL Series

Indications for Use:

CDL Series Medical Displays are intended for use in viewing digital medical images.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030276

Prescription Use ✓ OR Over-The-Counter Use

(Optional Format 1-2-96)